

## REMARKS

This Response is filed in response the Non-Final Office Action of August 19, 2009. Reconsideration and allowance of the application and all presently pending claims are respectfully requested.

Currently, claims 1-5 and 9-16 are pending in this application. Claims 1 and 11-14 have been amended. Claims 6-8 and 17-34 have been canceled. The prior art made of record has been considered, but is not believed to affect the patentability of the presently pending claims.

## CLAIMS

### **Claim 1**

Claim 1 is rejected under 35 U.S.C. §102(b) as purportedly anticipated by Feagin et al (Calc. Tiss. Res. 1969, 4, 231-244) as described in the Office Action. Claim 1 reads as follows:

1. A method of providing **vascular calcification therapy to a human** in need of treatment comprising the step of **administering to the human during dialysis a dialysate** having an effective amount of a pyrophosphate-type compound, **wherein the human has renal disease or failure.**

Applicants traverse the 102 rejection in the Office Action and submit that the rejection of claim 1 under 35 U.S.C. §102 in view of Feagin should be withdrawn because Feagin does not teach, disclose, or suggest each and every feature of claim 1 above. Specifically, Feagin does not teach, disclose, or suggest "providing vascular calcification therapy to a human ... administering to the human during dialysis a dialysate ... wherein the human has renal disease or failure", as recited in claim 1. Feagin teaches the demineralization of tooth enamel. Remineralization of partially demineralized tooth enamel is a very different process than vascular calcification. For example, tooth mineralization is a normal process while vascular calcification is abnormal. In addition, the tooth enamel in Feagin was already mineralized while vessels calcify de novo. Thus, the former examines propagation of hydroxyapatite crystals rather than initiation of hydroxyapatite formation. Furthermore, the

demineralized enamel is dead tissue since the demineralization process kills all cells. Vascular calcification occurs in living tissue. For at least these reasons, comparing Feagin to present disclosure is inappropriate since what is being done in Feagin is completely different than the features of claim 1.

In addition, it should be noted that Feagin found that two intraperitoneal pyrophosphate injections reduced the hardening of the partially demineralized enamel, but only in young rats or guinea pigs. There was no inhibition of hardening in adult animals. Vascular calcification occurs in older adult humans.

Moreover, Feagin did not demonstrate dialysis using pyrophosphate. Feagin removed plasma from animals and dialyzed the plasma against 0.15 M NaCl solutions. There was no pyrophosphate in the dialysate. Dialysis of plasma *ex vivo* in the laboratory is an entirely different procedure than dialysis of blood *in vivo*.

Thus, for at least the foregoing reason the rejection of claim 1 should be withdrawn since Feagin does not disclose each element of claim 1.

### ***Claims 3-5 and 9-13***

Claims 3-5 and 9-13 are rejected under 35 U.S.C. §102(a) and 103(a) as purportedly being anticipated or made obvious by the cited references. Applicants traverse the rejection and submit that pending dependent claims 3-5 and 9-13 include every feature of independent claim 1. Since the cited references fail to teach, disclose, or suggest each and every feature of claim 1, pending dependent claims 3-5 and 9-13 are also allowable over the cited references. *In re Fine*, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988).

Notwithstanding the reasons for allowance noted above, claim 5 is also allowable over the cited references for the following in reasons. The cited references do not teach, suggest, or disclose the features of claim 5 in view of the features of claim 1. The Office suggests one skilled in the art would be motivated to combine the teachings of Feagin and Qunibi and one skilled in the art would have a reasonable expectation for success in treating calcification caused by renal failure, as described in the Office Action. Applicants traverse this assertion. Qunibi discusses that pyrophosphate levels are elevated in patients with renal failure due to the inability to excrete pyrophosphate in

the urine and elevated pyrophosphate production secondary to hyperphosphatemia. Qunibi appears to suggest that the elevated pyrophosphate levels cause vascular calcification by inhibiting bone formation. In this regard, one skilled in the art would not find it obvious that a further elevation of pyrophosphate levels by adding it to dialysate would inhibit vascular calcification. In addition, one skilled in the art would not have a reasonable expectation of success treating calcification caused by renal failure using pyrophosphate based on the teachings of Qunibi. In fact it appears that Qunibi teaches away from the assertions the Office. Thus, for at least these reasons the rejection of claim 5 should be withdrawn.

#### **Claim 14**

Claim 14 is rejected under 35 U.S.C. §102(b) as purportedly anticipated by Feagin et al (Calc. Tiss. Res. 1969, 4, 231-244) as described in the Office Action. Claim 14 reads as follows:

14. A method of ***prophylactically treating vascular calcification*** comprising ***administering to a human in need of treatment during dialysis a dialysate*** having an effective amount of at least one pyrophosphate-type compound.

Applicants traverse the 102 rejection in the Office Action and submit that the rejection of claim 14 under 35 U.S.C. §102 in view of Feagin should be withdrawn because Feagin does not teach, disclose, or suggest each and every feature of claim 14 above. Specifically, Feagin does not teach, disclose, or suggest "prophylactically treating vascular calcification comprising administering to a human in need of treatment during dialysis a dialysate ... pyrophosphate-type compound", as recited in claim 14. Feagin teaches the demineralization of tooth enamel. Remineralization of partially demineralized tooth enamel is a very different process than vascular calcification. For example, tooth mineralization is a normal process while vascular calcification is abnormal. In addition, the tooth enamel in Feagin was already mineralized while vessels calcify de novo. Thus, the former examines propagation of hydroxyapatite

crystals rather than initiation of hydroxyapatite formation. Furthermore, the demineralized enamel is dead tissue since the demineralization process kills all cells. Vascular calcification occurs in living tissue. For at least these reasons, comparing Feagin to present disclosure is inappropriate since what is being done in Feagin is completely different than the features of claim 14. In addition, it should be noted that Feagin found that two intraperitoneal pyrophosphate injections reduced the hardening of the partially demineralized enamel, but only in young rats or guinea pigs. There was no inhibition of hardening in adult animals. Vascular calcification occurs in older adult humans. Moreover, Feagin did not demonstrate dialysis using pyrophosphate. Feagin removed plasma from animals and dialyzed the plasma against 0.15 M NaCl solutions. There was no pyrophosphate in the dialysate. Dialysis of plasma ex vivo in the laboratory is an entirely different procedure than dialysis of blood in vivo. Thus, for at least the foregoing reason the rejection of claim 14 should be withdrawn since Feagin does not disclose each element of claim 14.

#### ***Claims 15 and 16***

Claims 15 and 16 are rejected under 35 U.S.C. §102(a) and 103(a) as purportedly being anticipated or made obvious by the cited references. Applicants traverse the rejection and submit that pending dependent claims 15 and 16 include every feature of independent claim 14. Since the cited references fail to teach, disclose, or suggest each and every feature of claim 14, pending dependent claims 15 and 16 are also allowable over the cited references. *In re Fine*, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988).

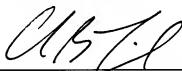
### **CONCLUSION**

In light of the reasons set forth above, Applicants respectfully submit that all objections and/or rejections have been traversed, rendered moot, and/or accommodated. Favorable reconsideration and allowance of the present application and all pending claims are hereby courteously requested.

In addition, any other statements in the Office Action that are not explicitly addressed herein are not intended to be admitted. In addition, any and all findings of inherency are traversed as not having been shown to be present. Furthermore, any and all findings of well-known art and official notice, or statements interpreted similarly, should not be considered well known.

If, in the opinion of the Examiner, a telephonic conference would expedite the examination of this matter, the Examiner is invited to call the undersigned attorney at (770) 933-9500.

Respectfully submitted,



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